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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/631,638	08/02/2000	Kevin M. Moore	1533.0980001/SRL/PAJ	8662

7590 06/02/2004

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EXAMINER

NAFF, DAVID M

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 06/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)	
09/631,638	MOORE ET AL.	
Examiner	Art Unit	
David M. Naff	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 19 April 2004.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1,5-7,9-17 and 21-31 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1, 5-7, 9-17 & 21-31 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.

4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) Notice of Informal Patent Application (PTO-152)
6) Other: _____.

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application 5 after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/19/04 has been entered.

0 An amendment of 4/19/04 amended claims 1 and 17. It is noted that claimed 17 is listed as previously amended. However, the claim is currently amended in step (a).

Claims examined on the merits are 1, 5-7, 9-17 and 21-31 which are all claims in the application.

5 The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

0 The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5 Claims 1, 5-7, 9, 10, 13-17, 21-25 and 28-31 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being

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enabling for strong acid in step (c) of claims 1 and 17, does not reasonably provide enablement for an acid that is not a strong acid. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification discloses only strong acids that allow for selective recovery of the organic acid (paragraph bridging pages 8 and 9). It would be speculation and unpredictable as to another acid that will provide the desired recovery. It is suggested that line 2 of step (c) of claim 1 be amended by changing "an acid" to --- a strong acid ---, and canceling ", wherein said acid can be any acid". With this change, line 2 of claim 9 should be amended by inserting --- strong --- before "acid". Corresponding amendments should be made to claims 17 and 25.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 5-7, 9-17 and 21-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Step (a) of claim 1 is confusing and unclear by requiring the broth to contain an organic acid and microbial biomass without a

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preceding step of fermenting with a microorganism to produce the organic acid and microbial biomass in the broth. It is unclear as to the relationship of the organic acid and the microbial biomass to the fermentation, and the source of the acid and biomass in the broth is 5 unclear. It is suggested that claim 1 be amended as follows: line 2, after "broth" insert --- resulting from fermentation with a microorganism to produce said organic acid ---, change step (a) to read --- conducting a fermentation with an organic acid producing microorganism to produce a fermentation broth containing said organic 10 acid and insolubles comprising all microbial biomass resulting from said fermentation with said microorganism ---, step (b) should be changed to read --- drying said fermentation broth to obtain a dried product containing said organic acid and said insolubles comprising said microbial biomass, wherein said drying occurs without prior 15 removal of any of said insolubles comprising said microbial biomass from said fermentation broth ---, and change step (d) to read --- removing said insolubles comprising said microbial biomass to obtain said organic acid ---.

Dependent claims 6-13 and 16 are confusing in that the steps 20 further limited have not been changed to correspond to the change in the steps of claim 1 by amendment. In claims 5, 7, 9, 10, 11 and 12, "b" should be --- c --. In claim 6, "a" should be --- b ---, and in claims 13 and 16, "c" should be --- d ---.

Dependent claim 7 is confusing by not having clear antecedent 25 basis for "the reaction". A reaction is not required in claim 1. It

is suggested that "reaction" be canceled. This change should also be made to claim 23 for the same reason.

Claim 17 is confusing and unclear by step (a) requiring a broth containing an organic acid, and drying without prior removal of 5 insolubles to produce a dried product containing all of the biomass, and not requiring a previous step of fermenting with an organic acid producing microorganism to produce a fermentation broth containing the organic acid, insolubles and microbial biomass. There is no antecedent basis for insolubles and biomass, and the relationship of 10 the insolubles and biomass to each other and to the fermentation broth is unclear. It is suggested that claim 17 be amended in the same type of way as suggested above for claim 1. Additionally, in line 1 of claim 26, --- acid --- should be inserted after "said".

Claim Rejections - 35 USC § 103

15 Claims 1, 5-7, 9-17 and 21-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dumpelmann et al (5,852,211) in view of Bott et al (0 174 624) for the type of reasons set forth in the previous office action of 11/19/03, and for reasons herein.

20 The claims are drawn to recovery of an organic acid from a fermentation broth by drying the broth without prior removal of microbial biomass (claim 1) or insolubles (claim 17) from the broth to produce a dried product, adding the dried product to a lower alcohol in the presence of an acid and removing insolubles by to obtain the organic acid. The organic acid can be 2-keto-L-gulonic acid and the

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acid present when the dry product is added to the lower alcohol can be sulphuric acid.

Dumpelmann et al disclose a process for obtaining 2-keto-L-gulonic acid (KGA) from a fermentation solution containing the sodium salt of 2-keto-L-gulonic acid (NaKGA) that results from neutralization. The process involves crystallizing the sodium salt (NaKGA) and separating the resulting crystals from the fermentation solution, suspending the NaKGA crystals in a lower alcohol acidified to a pH of about 1.5 to about 3.5 with an acid such as sulphuric acid where the acid is converted to an insoluble sodium salt and the NaKGA is converted to free KGA, and removing the insoluble sodium salt of the acid to obtain an alcoholic solution of the KGA. Afterwards, the free KGA may be esterified by alcohol of the alcoholic solution in the presence of a catalytic amount of acid to obtain an alkyl ester of the KGA. For example, see col 4, lines 10-33, and Examples 1-3.

Bott et al disclose producing alkyl lactate esters by filtering a crude fermentation mixture containing calcium lactate, spray drying the resulting filtrate to obtain solid calcium lactate, reacting the solid calcium lactate with an alcohol in the presence of an acid that forms a water-soluble calcium salt and isolating the lactic acid ester formed.

It would have been obvious to omit crystallizing NaKGA in the process of Dumpelmann et al and instead dry the fermentation broth and react the dried broth with the lower alcohol in the presence of acid as suggested by Bott et al using steps of drying a fermentation

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solution without crystallizing in the production of a lactic acid ester from a fermentation mixture containing a calcium salt of the lactic acid. Drying without crystallizing would have been expected to simplify the process of Dumpelmann et al, and such simplification would have been motivation to use drying in place of crystallizing and separating the crystals. While Bott et al filters the fermentation broth, it would have been obvious to omit filtering to further simplify. There is seen nothing to lead one to believe that the reacting of NaKGA as disclosed by Bott et al cannot occur in an unfiltered fermentation broth.

Response to Arguments

Applicant's arguments and 132 Declaration filed 4/19/04 have been fully considered but they are not persuasive.

Applicants point out that the claims have been amended to require fermentation to produce a broth containing an organic acid and microbial biomass, and drying the broth without prior removal of the microbial biomass. However, in step (a) of claim 1, there is no requirement for biomass to be result from fermentation with a microorganism to produce the broth, and the claim does not require all biomass resulting from fermentation to be present. The microbial biomass in claim 1 can be only a small amount remaining after removal of at least 90% insolubles as disclosed in the specification (page 7, lines 14-16). This also applies to claim 17. Even if Example 1 in the specification is carried out as stated in the declaration, the claims do not require all microbial biomass and insolubles resulting

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from fermenting with a microorganism to remain in the broth when drying is carried out. The claims do not exclude filtering after fermenting to remove at least 90% insolubles containing microbial biomass since this can occur in step (a) of claim 1 after the fermentation, or prior to step (a) of claim 17.

While Bott et al filters to remove biomass, Dumpelmann et al does not have to remove biomass prior to crystallizing (col 5, lines 1-5). In any event, as noted above, the claims do not require all insolubles containing microbial biomass resulting from fermentation with a microorganism to produce the acid to be present in the broth dried.

Conclusion

The claims would be free of the prior art if amended as set forth above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David M. Naff
Primary Examiner
Art Unit 1651

DMN

5/28/04